DEPARTMENT OF DEFENSE **BILLING CODE 5001-06**

Office of the Secretary

32 CFR Part 199

DOD-2013-HA-0164

RIN 0720-AB61

TRICARE; Coverage of Care Related to Non-Covered Initial Surgery or Treatment

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Proposed rule.

SUMMARY: The Department of Defense (DoD) is publishing this proposed rule to allow coverage for otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae), as well as medically necessary and appropriate follow-on care, resulting from a non-covered incident of treatment provided pursuant to a properly granted Supplemental Health Care Program waiver. This proposed rule is necessary to protect TRICARE beneficiaries from incurring financial hardships due to the current regulatory restrictions that prohibit TRICARE coverage of the treatment of complications resulting from non-covered medical procedures, even when those procedures were provided while the beneficiary was an active duty member and were authorized by the Director, TRICARE Management Activity (TMA), based on a determination that a waiver authorizing the original non-covered surgery or treatment was necessary to assure adequate availability of health care to the Active Duty member. Additionally, with respect to care that is related to a non-covered initial surgery or treatment, the proposed rule seeks to eliminate any confusion regarding what services and

supplies will be covered by TRICARE and under what circumstances they will be covered.

DATES: Comments must be received on or before [INSERT 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Do not submit comments directly to the point of contact or mail your comments to any address other than what is shown below. Doing so will delay the posting of the submission.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Identification Number (RIN) and title, by any of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350-3100.

Instructions: All submissions received must include the agency name and docket number or RIN for this Federal Register document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at http://regulations.gov as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Thomas Doss (703) 681-7512.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

1. Purpose of Regulatory Actions

a. Need for Regulatory Actions

Under the TRICARE private sector health care program, certain conditions and treatments are excluded from coverage. For example, any drug, device, medical treatment, or procedure whose safety and efficacy has not been established by reliable evidence is considered unproven and excluded from coverage. This exclusion includes all services directly related to the unproven drug, device, medical treatment or procedure. Specifically, benefits for otherwise covered services and supplies that are required in the treatment of complications (unfortunate sequelae) resulting from a non-covered incident of treatment, are generally excluded from TRICARE coverage pursuant to title 32 of the Code of Federal Regulation (CFR) section 199.4(e)(9), unless the complication represents a separate medical condition such as a systemic infection, cardiac arrest, and acute drug reaction. TRICARE also excludes any needed follow-on care resulting from a non-covered condition or initial surgery or treatment pursuant to §199.4(g)(63).

There is currently one exception to this general exclusion, published in the Federal Register [76 FR 57642] on September 16, 2011, to allow coverage of otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae) resulting from a non-covered incident of treatment provided in a Military Treatment Facility (MTF), when the initial non-covered service has been authorized by the MTF Commander and the MTF is unable to provide the necessary treatment of the complications. This current exception recognizes that in order to support Graduate Medical Education and maintain provider skill levels, MTF providers are required to perform medical procedures that may be excluded from coverage under the TRICARE private sector program. The final rule at 32 CFR199.4(e)(9)(ii) was viewed as necessary to protect TRICARE beneficiaries from incurring financial hardships in such cases.

Currently, Active Duty Service members (ADSMs) may receive non-covered TRICARE private sector health care services under the Supplemental Health Care Program (SHCP) if a waiver is submitted through the Service and approved by the Director, TMA, or designee, in accordance with §199.6(f). While the Department wants to ensure that Service members have access to the latest, promising medical technologies and procedures, there must be assurance that the care is safe and effective, and that members are not subjected to undue risk, or rendered unfit for continued service, due to complications suffered as a result of unproven medical care. Consequently, requests for non-covered procedures and treatments, including unproven care, are carefully reviewed in conjunction with other available, proven treatments, if any exist, to determine whether or not approval of the requested care is necessary to assure the adequate availability of health care to the member. Currently, Service members are counseled that the treatment remains a non-covered TRICARE benefit, and that any follow-on care, including care for complications, will not be covered by TRICARE once the member separates or retires. Members are left to make a difficult choice between pursuing a SHCP waiver in an effort to remain fit for full duty while assuming the financial risk of any necessary follow-on care after discharge, or, electing not to receive the care and risk separation from the Service.

Like the existing exception at 32 CFR199.4(e)(9)(ii) for non-covered care provided in a MTF, this proposed exception is narrowly tailored to serve a similar government interest; namely, protecting former active duty members who have received private sector care pursuant to a SHCP waiver in an effort to ensure their fitness for duty and continued service.

Additionally, some confusion has arisen regarding the terms ‘complication” and “unfortunate sequelae” as these terms are not currently defined in regulation. Questions have arisen with respect to whether necessary follow-on care resulting from a non-covered procedure or treatment in an MTF is covered in situations where the MTF is unable to provide the necessary treatment. The intent of the original September 16, 2011, final rule, as well as the current proposal, is to protect TRICARE beneficiaries from incurring financial hardships in limited circumstances, which serve valid governmental purposes. Absent an exception to the general exclusion from coverage, treatment of adverse outcomes, both expected and unexpected, as well as any necessary follow-on care that is a direct result of the initial non-covered treatment, are excluded and could result in less than optimal care (e.g., not receiving necessary physical therapy following surgery) and/or a significant financial hardship for the beneficiary. The Agency did not intend to prevent coverage of necessary follow-on private sector care in situations where an MTF is unable to provide that care but the current regulatory language is subject to such a narrow interpretation absent additional clarification. This proposal would permit coverage of necessary continued treatment, such as physical therapy following a non-covered surgical procedure in an MTF. It would also cover medically necessary follow-on care, including, for example, anti-rejection medications for former members who have received face and hand transplants. This proposal will eliminate the need to try to determine whether the medically necessary and appropriate care the patient is seeking from the private sector is considered to be treatment of an expected complication, an unexpected complication or routine follow-on care, because it will be clearly covered.

b. Legal Authority for the Regulatory Action

This regulation is proposed under the authority of 10 U.S.C. section 1073, which authorizes the Secretary of Defense to administer the medical and dental benefits provided in chapter 55 of title 10, United States Code. The Department is authorized to provide medically necessary and appropriate treatment for mental and physical illnesses, injuries and bodily malfunctions, including hospitalization, outpatient care, drugs, treatment of medical and surgical conditions and other types of health care outlined in 10 U.S.C. section 1077(a). Although section 1077 defines benefits to be provided in the MTFs, these benefits are incorporated by reference for the benefits provided in the civilian health care sector to active duty family members and retirees and their dependents through section 1079 and 1086 respectively.

2. Summary of Major Provisions of the Regulatory Action

The proposed rule amends the existing special benefit provision regarding complications (unfortunate sequelae) resulting from non-covered initial surgery, to more clearly address what services and supplies will be covered by TRICARE and under what circumstances they will be covered. The provision itself is relabeled "Care related to non-covered initial surgery or treatment" to eliminate any confusion regarding what constitutes a complication or unfortunate sequelae and how broadly or narrowly the exclusion and exceptions to the exclusion should be applied. As amended, the regulatory section will specifically address coverage of otherwise covered medically necessary treatment, to include (i) coverage of complications that represent a separate medical condition; (ii) treatment of complications and necessary follow-on care resulting from a non-covered incident of treatment provided in an MTF; and (iii) treatment of complications and necessary follow-on care resulting from a non-covered incident of

treatment provided pursuant to an approved SHCP waiver. Inclusion of the third prong will support the provision of care necessary to allow members to return to full duty and/or reach their maximum rehabilitative potential without requiring the member to bear the sole financial risk for unfortunate sequelae once they are no longer on active duty. This amendment provides consistent treatment of unfortunate sequelae and necessary follow-on care when an original episode of non-covered care is provided for a valid governmental purpose, whether to support Graduate Medical Education (GME) and maintain provider skill levels within an MTF or an ADSM's fitness for duty through authorization of the purchase of otherwise non-covered care via an SHCP waiver. Additionally, the regulatory exclusion at 32 CFR 199.4(g)(63) is amended to clearly state that all services and supplies related to a non-covered condition or treatment, including any necessary follow-on care and treatment of complications, are excluded from coverage except as provided in 32 CFR 199.4(e)(9).

3. Summary of Costs and Benefits

This proposed rule is not anticipated to have an annual effect on the economy of $100 million or more; therefore, it is not an economically significant rule under Executive Order 12866 and the Congressional Review Act. All services and supplies authorized under the TRICARE Basic Program must be determined to be medically necessary in the treatment of an illness, injury or bodily malfunction before the care can be cost shared by TRICARE. For this reason, DoD anticipates that TRICARE will have a marginal increase in cost associated with the inclusion of coverage for treatment of complications and necessary follow-on care for TRICARE beneficiaries who received

previously authorized non-covered treatment pursuant to a SHCP waiver while on active duty.

II. Background

Members of the uniformed services on active duty are entitled to medical and dental care pursuant to 10 U.S.C. 1074, including the provision of such care in private facilities. 32 CFR199.16 implements, with respect to the purchase of private sector health care services for ADSMs under the SCHP, the statutory authority at 10 U.S.C. 1074(c). As a general rule, the same rules that govern payment and administration of private sector health care claims under TRICARE apply to the SHCP and the care that members receive in private facilities is comparable to coverage for medical care under the TRICARE Prime program. 32 CFR 199.16(f) authorizes the Director of TRICARE Management Activity (TMA) discretionary authority to waive any requirements of TRICARE regulations, including any restrictions or limitations under the TRICARE Basic Program benefits, except those specifically set forth in statute, based on "a determination that such waiver is necessary to assure adequate availability of health care to Active Duty members." ADSMs have access to non-covered care including experimental or unproven medical care and treatments in the purchased care sector on a case-by-case basis using the SHCP waiver process. These case-by-case treatment decisions are specifically approved by the Director or Deputy Director of the TRICARE Management Activity, resulting in a number of ADSMs receiving otherwise non-covered private sector care while serving.

If an ADSM is granted a waiver under the SCHP to receive an otherwise non-covered incident of treatment by a private sector provider, rather than in an MTF, and suffers complications from the care, SHCP funds can be used to cover necessary follow-

on care and treatment of complications in the purchased care system as long as the member remains on active duty. Once the member retires, however, SHCP coverage no longer exists and TRICARE does not cover unfortunate sequelae of non-covered care done in the purchased care sector except in limited circumstances (e.g. later complications that represent a separate medical condition separate from the condition that the non-covered treatment or surgery was directed toward, and the treatment of the complication is not essentially similar to the covered procedures. This may include a systemic infection, cardiac arrest, or acute drug reaction). Additionally, once retired, existing regulations would not allow the continuation of any needed follow-on care such as rehabilitative care or drug therapy. When these beneficiaries require such treatment, they are responsible for the payment for this necessary treatment resulting in significant financial hardship. This rule will address that unfortunate situation by allowing coverage of treatment for necessary follow-on care, including complications, resulting from the non-covered treatment provided to beneficiaries pursuant to a SHCP waiver while they were on active duty. The specific procedures for approval of this treatment will be addressed in the TRICARE Policy Manual rather than in the regulation to ensure that this information is current and easily accessible. TRICARE manuals may be accessed at http://www.tricare.mil.

III. Regulatory Procedure

Executive Order 12866, "Regulatory Planning and Review" and EO 13563, "Improving Regulation and Regulatory Review"

It has been determined that this proposed rule is not a significant regulatory action. This rule does not:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribunal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in these Executive Orders.

Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104-4)

It has been certified that this proposed rule does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of $100 million or more in any one year.

Pub.L. 96-354, "Regulatory Flexibility Act" (5 U.S.C. 601)

It has been certified that this proposed rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Set forth in the proposed rule are minor revisions to the existing regulation. The DoD does not anticipate a significant impact on the Program.

Pub.L. 96-511, "Paperwork Reduction Act" (44 U.S.C. Chapter 35)

It has been certified that this proposed rule does not impose reporting or recordkeeping requirements under the Paperwork Act of 1995.

Executive Order 13132, Federalism

It has been certified that this proposed rule does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

(1) The States;

(2) The relationship between the National Government and the States; or

(3) The distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, and Military personnel.

Accordingly, 32 CFR part 199 is proposed to be amended to read as follows:

Part 199-- [AMENDED]

1. The authority citation for part 199 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. chapter 55.

2. Amend § 199.4 by revising paragraphs (e)(9) and (g)(63) to read as follows:

§ 199.4 Basic Program Benefits

* * * * *

(e) * * *

(9) Care related to non-covered initial surgery or treatment. (i) Benefits are available for otherwise covered services and supplies required in the treatment of complications resulting from a non-covered incident of treatment (such as nonadjunctive dental care or cosmetic surgery) but only if, the later complication represents a separate medical condition such as a systemic infection, cardiac arrest, and acute drug reaction. Benefits

may not be extended for any later care or a procedure related to the complication that essentially is similar to the initial non-covered care. Examples of complications similar to the initial episode of care (and thus not covered) would be repair of facial scarring resulting from dermabrasion for acne.

(ii) Benefits are available for otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae) and any necessary follow-on care resulting from a non-covered incident of treatment provided in an MTF, when the initial non-covered service has been authorized by the MTF Commander and the MTF is unable to provide the necessary treatment of the complications or required follow-on care, according to the guidelines adopted by the Director, TMA, or a designee.

(iii) Benefits are available for otherwise covered services and supplies required in the treatment of complications (unfortunate sequelae) and any necessary follow-on care resulting from a non-covered incident of treatment provided in the private sector pursuant to a properly granted waiver under § 199.16(f) of this chapter. The Director, TMA, or designee, shall issue guidelines for implementing this provision.

* * * * *

(g) * * *

(63) Non-covered condition/treatment, unauthorized provider. All services and supplies (including inpatient institutional costs) related to a non-covered condition or treatment, including any necessary follow-on care or the treatment of complications, are excluded from coverage except as provided in under paragraph (e)(9) of this section. In addition, all services and supplies provided by an unauthorized provider are excluded.

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Dated: September 26, 2013.

Patricia L. Toppings,

OSD Federal Register Liaison Officer

Department of Defense

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